Attachment I 510(k) Summary K093013

This 510(k) Summary is prepared per the request of 21 CFR 807.92.

The assigned 510(k) Number is K093013

JAN - 8 2010

Date of Preparation	December 22, 2009
Sponsor	**Beijing Choice Electronic Technology Co., Ltd** Bailangyuan Bldg B 1127-1128, Fuxing road, A36, Beijing, 100039, China Contact Person: Mr. Lei Chen;
Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No.19, Lane 999, Zhongshan Road (S-2), Shanghai, 200030, China
Proposed Device Classification	Blood Pressure Monitor, MD 200A System, Measurement, Blood-pressure, Non-invasive DXN, 870.1130, Class II
Intended Use	MD200A Blood Pressure Monitor is an automatic electronic blood pressure monitor intended to measure the systolic, diastolic and mean blood pressure as well as pulse rate via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used on adult, pediatric and neonatal individuals.
Device Description	MD200A Blood Pressure Monitor is a handheld device, which can connected to the blood pressure cuff with various specifications, intended for measuring the systolic, diastolic and mean blood pressure as well as pulse rate via non-invasive oscillometric technique.
Testing	Performance testing including clinical and bench testing was conducted to validate and verify that the proposed device, MD200A Blood Pressure Monitor met all design specifications and was substantially equivalent to the predicate device.
Predicate Device	Microlife Upper Arm Automatic Digital Blood Pressure Monitor, **K082881**
SE Conclusion	The proposed device, MD200A Blood Pressure Monitor is substantially equivalent (SE) to the predicate device, Microlife Upper Arm Automatic Digital Blood Pressure Monitor, **K082881.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 8 2010

Beijing Choice Electronic Technology Co., Ltd
c/o Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 5D, No. 19, Lane 999, Zhongshan Road
Shanghai 200030
CHINA

Re: K093013
Trade/Device Name: MD200A Blood Pressure Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: December 22, 2009
Received: December 24, 2009

Dear Mr. Fu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment II Indication for Use Form

510(k) Number: K093013

Device Name: MD200A Blood Pressure Monitor

Indications for Use:

MD200A Blood Pressure Monitor is an automatic electronic blood pressure monitor intended to measure the systolic, diastolic and mean blood pressure as well as pulse rate via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used on adult, pediatric and neonatal individuals.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over -The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093013